

US EPA ARCHIVE DOCUMENT



# Reregistration Eligibility Decision (RED)

## Mitin FF





## UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

### CERTIFIED MAIL

Dear Registrant:

I am pleased to announce that the Environmental Protection Agency has completed its reregistration eligibility review and decisions on the pesticide chemical case Mitin FF which includes the active ingredient Sodium 5-chloro-2-(4-chloro-2- [(3,4-dichlorophenyl)ureido] phenoxy) benzenesulfonate. The enclosed Reregistration Eligibility Decision (RED) contains the Agency's evaluation of the data base for this chemical, its conclusions of the potential human health and environmental risks of the current product uses, and its decisions and conditions under which these uses and products will be eligible for reregistration. The RED includes the data and labeling requirements for products for reregistration. It may also include requirements for additional data (generic) on the active ingredient to confirm the risk assessments.

To assist you with a proper response, read the enclosed document entitled "Summary of Instructions for Responding to the RED." This summary also refers to other enclosed documents which include further instructions. You must follow all instructions and submit complete and timely responses. **The first set of required responses is due 90 days from the receipt of this letter. The second set of required responses is due 8 months from the receipt of this letter.** Complete and timely responses will avoid the Agency taking the enforcement action of suspension against your products.

Please note that this RED was finalized and signed prior to August 3, 1996. On that date, the Food Quality Protection Act of 1996 ("FQPA") became effective, amending portions of both the pesticide law (FIFRA) and the food and drug law (FFDCA). This RED does not address any issues raised by FQPA, and any tolerance-related statements in the RED did not take into account any changes in tolerance assessment procedures required under FQPA. To the extent that this RED indicates that a change in any tolerance is necessary, that determination will be reassessed by the Agency under the standards set forth in FQPA before a proposed tolerance is issued. To the extent that the RED does not indicate that a change in the tolerance is necessary, that tolerance, too, will be reassessed in the future pursuant to the requirements of FQPA.

If you have questions on the product specific data requirements or wish to meet with the Agency, please contact the Special Review and Reregistration Division representative Veronica Dutch (703) 308-8585.

Sincerely yours,

Lois Rossi, Division Director  
Special Review  
and Reregistration Division

Enclosures

**SUMMARY OF INSTRUCTIONS FOR RESPONDING TO  
THE REREGISTRATION ELIGIBILITY DECISION (RED)**

1. **DATA CALL-IN (DCI) OR "90-DAY RESPONSE"**--If **generic data** are required for reregistration, a DCI letter will be enclosed describing such data. If **product specific data** are required, a DCI letter will be enclosed listing such requirements. If **both generic and product specific data** are required, a combined Generic and Product Specific DCI letter will be enclosed describing such data. However, if you are an end-use product registrant only and have been granted a generic data exemption (GDE) by EPA, you are being sent only the **product specific** response forms (2 forms) with the RED. Registrants responsible for generic data are being sent response forms for both generic and product specific data requirements (4 forms). **You must submit the appropriate response forms (following the instructions provided) within 90 days of the receipt of this RED/DCI letter; otherwise, your product may be suspended.**

2. **TIME EXTENSIONS AND DATA WAIVER REQUESTS**--No time extension requests will be granted for the 90-day response. Time extension requests may be submitted only with respect to actual data submissions. Requests for time extensions for product specific data should be submitted in the 90-day response. Requests for data waivers must be submitted as part of the 90-day response. All data waiver and time extension requests must be accompanied by a full justification. All waivers and time extensions must be granted by EPA in order to go into effect.

3. **APPLICATION FOR REREGISTRATION OR "8-MONTH RESPONSE"**--**You must submit the following items for each product within eight months of the date of this letter (RED issuance date).**

a. **Application for Reregistration** (EPA Form 8570-1). Use only an original application form. Mark it "Application for Reregistration." Send your Application for Reregistration (along with the other forms listed in b-e below) to the address listed in item 5.

b. **Five copies of draft labeling** which complies with the RED and current regulations and requirements. Only make labeling changes which are required by the RED and current regulations (40 CFR 156.10) and policies. Submit any other amendments (such as formulation changes, or labeling changes not related to reregistration) separately. You may, but are not required to, delete uses which the RED says are ineligible for reregistration. For further labeling guidance, refer to the labeling section of the EPA publication "General Information on Applying for Registration in the U.S., Second Edition, August 1992" (available from the National Technical Information Service, publication #PB92-221811; telephone number 703-487-4650).

c. **Generic or Product Specific Data**. Submit all data in a format which complies with PR Notice 86-5, and/or submit citations of data already submitted and give the EPA identifier (MRID) numbers. Before citing these studies, you must **make sure that they meet the Agency's acceptance criteria** (attached to the DCI).

d. **Two copies of the Confidential Statement of Formula (CSF)** for each basic and each alternate formulation. The labeling and CSF which you submit for each product must comply with P.R. Notice 91-2 by declaring the active ingredient as the **nominal concentration**. You have two options for submitting a CSF: (1) accept the standard certified limits (see 40 CFR §158.175) or (2) provide certified limits that are supported by the analysis of five batches. If you choose the second option, you must submit or cite the data for the five batches along with a certification statement as described in 40 CFR §158.175(e). A copy of the CSF is enclosed; follow the instructions on its back.

e. **Certification With Respect to Data Compensation Requirements**. Complete and sign EPA form 8570-31 for each product.

4. **COMMENTS IN RESPONSE TO FEDERAL REGISTER NOTICE**--Comments pertaining to the content of the RED may be submitted to the address shown in the Federal Register Notice which announces the availability of this RED.

5. **WHERE TO SEND PRODUCT SPECIFIC DCI RESPONSES (90-DAY) AND APPLICATIONS FOR REREGISTRATION (8-MONTH RESPONSES)**

**By U.S. Mail:**

Document Processing Desk (**RED-SRRD-PRB**)  
Office of Pesticide Programs (7504C)  
EPA, 401 M St. S.W.  
Washington, D.C. 20460-0001

**By express:**

Document Processing Desk (**RED-SRRD-PRB**)  
Office of Pesticide Programs (7504C)  
Room 266A, Crystal Mall 2  
1921 Jefferson Davis Hwy.  
Arlington, VA 22202

6. **EPA'S REVIEWS**--EPA will screen all submissions for completeness; those which are not complete will be returned with a request for corrections. EPA will try to respond to data waiver and time extension requests within 60 days. EPA will also try to respond to all 8-month submissions with a final reregistration determination within 14 months after the RED has been issued.

**REREGISTRATION ELIGIBILITY DECISION**

**Mitin FF**

**LIST C**

**CASE 3097**



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## **REREGISTRATION ELIGIBILITY DECISION TEAM FOR MITIN FF**

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## GLOSSARY OF TERMS AND ABBREVIATIONS

ADI	Acceptable Daily Intake. A now defunct term for reference dose (RfD).
AE	Acid Equivalent
a.i.	Active Ingredient
ARC	Anticipated Residue Contribution
CAS	Chemical Abstracts Service
CI	Cation
CNS	Central Nervous System
CSF	Confidential Statement of Formula
DFR	Dislodgeable Foliar Residue
DRES	Dietary Risk Evaluation System
DWEL	Drinking Water Equivalent Level (DWEL) The DWEL represents a medium specific (i.e. drinking water) lifetime exposure at which adverse, non carcinogenic health effects are not anticipated to occur.
EEC	Estimated Environmental Concentration. The estimated pesticide concentration in an environment, such as a terrestrial ecosystem.
EP	End-Use Product
EPA	U.S. Environmental Protection Agency
FDA	Food and Drug Administration
FIFRA	Federal Insecticide, Fungicide, and Rodenticide Act
FFDCA	Federal Food, Drug, and Cosmetic Act
FOB	Functional Observation Battery
GLC	Gas Liquid Chromatography
GM	Geometric Mean
GRAS	Generally Recognized as Safe as Designated by FDA
HA	Health Advisory (HA). The HA values are used as informal guidance to municipalities and other organizations when emergency spills or contamination situations occur.
HDT	Highest Dose Tested
LC <sub>50</sub>	Median Lethal Concentration. A statistically derived concentration of a substance that can be expected to cause death in 50% of test animals. It is usually expressed as the weight of substance per weight or volume of water, air or feed, e.g., mg/l, mg/kg or ppm.
LD <sub>50</sub>	Median Lethal Dose. A statistically derived single dose that can be expected to cause death in 50% of the test animals when administered by the route indicated (oral, dermal, inhalation). It is expressed as a weight of substance per unit weight of animal, e.g., mg/kg.
LD <sub>10</sub>	Lethal Dose-low. Lowest Dose at which lethality occurs.
LEL	Lowest Effect Level
LOC	Level of Concern
LOD	Limit of Detection
LOEL	Lowest Observed Effect Level
MATC	Maximum Acceptable Toxicant Concentration
MCLG	Maximum Contaminant Level Goal (MCLG) The MCLG is used by the Agency to regulate contaminants in drinking water under the Safe Drinking Water Act.
µg/g	Micrograms Per Gram
mg/L	Milligrams Per Liter
MOE	Margin of Exposure
MP	Manufacturing-Use Product
MPI	Maximum Permissible Intake
MRID	Master Record Identification (number). EPA's system of recording and tracking studies submitted.
N/A	Not Applicable
NOEC	No effect concentration

## GLOSSARY OF TERMS AND ABBREVIATIONS

NPDES	National Pollutant Discharge Elimination System
NOEL	No Observed Effect Level
NOAEL	No Observed Adverse Effect Level
OP	Organophosphate
OPP	Office of Pesticide Programs
PADI	Provisional Acceptable Daily Intake
PAG	Pesticide Assessment Guideline
PAM	Pesticide Analytical Method
PHED	Pesticide Handler's Exposure Data
PHI	Preharvest Interval
ppb	Parts Per Billion
PPE	Personal Protective Equipment
ppm	Parts Per Million
PRN	Pesticide Registration Notice
$Q^*_1$	The Carcinogenic Potential of a Compound, Quantified by the EPA's Cancer Risk Model
RBC	Red Blood Cell
RED	Reregistration Eligibility Decision
REI	Restricted Entry Interval
RfD	Reference Dose
RS	Registration Standard
SLN	Special Local Need (Registrations Under Section 24 (c) of FIFRA)
TC	Toxic Concentration. The concentration at which a substance produces a toxic effect.
TD	Toxic Dose. The dose at which a substance produces a toxic effect.
TEP	Typical End-Use Product
TGAI	Technical Grade Active Ingredient
TLC	Thin Layer Chromatography
TMRC	Theoretical Maximum Residue Contribution
torr	A unit of pressure needed to support a column of mercury 1 mm high under standard conditions.
FAO/WHO	Food and Agriculture Organization/World Health Organization
WP	Wettable Powder
WPS	Worker Protection Standard

## EXECUTIVE SUMMARY

This Reregistration Eligibility Decision (RED) addresses the eligibility for reregistration of the pesticide product containing the active ingredient Mitin FF (sodium 5-chloro-2-(4-chloro-2-[(3,4-dichlorophenyl) ureido] phenoxy) benzenesulfonate). Mitin FF is used to moth-proof wool. It is used in the textile industry as an 80 percent formulation of the active ingredient applied to wool during the dyeing/manufacturing process. Only one product containing Mitin FF as the sole active ingredient is currently registered.

The Agency has completed its review of the target database for Mitin FF and has determined that the use of Mitin FF as labeled and specified in the RED will not cause unreasonable risk to humans or to the environment and its one use is eligible for reregistration.

The Agency has identified no human toxicological endpoints of regulatory concern for Mitin FF. While the hazard to nontarget organisms from Mitin FF has been characterized, a risk assessment has not been conducted. The risk to aquatic-environments from Mitin FF is regulated under the NPDES permitting program of the Agency's Office of Water. No additional data are required by the Agency to confirm its conclusions. Supporting data demonstrates this chemical has low to moderate acute mammalian toxicity, and does not cause significant subchronic, mutagenic, or developmental effects. Environmental data shows Mitin FF has low to moderate acute toxicity to wildlife species. Mitin FF was found to be stable to hydrolysis.

Before reregistering the product containing Mitin FF, the Agency is requiring that product specific data, revised Confidential Statement of Formula (CSF) and revised labeling be submitted within eight months of the issuance of this document. These data include product chemistry and acute toxicity testing. After reviewing these data and any revised labels and finding them acceptable in accordance with Section 3(c)(5) of FIFRA, the Agency will reregister the product.



## I. INTRODUCTION

In 1988, the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) was amended to accelerate the reregistration of products with active ingredients registered prior to November 1, 1984. The amended Act provides a schedule for the reregistration process to be completed in nine years. There are five phases to the reregistration process. The first four phases of the process focus on identification of data requirements to support the reregistration of an active ingredient and the generation and submission of data to fulfill the requirements. The fifth phase is a review by the U.S. Environmental Protection Agency (referred to as "the Agency") of all data submitted to support reregistration.

FIFRA Section 4(g)(2)(A) states that in Phase 5 "the Administrator shall determine whether pesticides containing such active ingredient are eligible for reregistration" before calling in data on products and either reregistering products or taking "other appropriate regulatory action." Thus, reregistration involves a thorough review of the scientific data base underlying a pesticide's registration. The purpose of the Agency's review is to reassess the potential hazards arising from the currently registered uses of the pesticide; to determine the need for additional data on health and environmental effects; and to determine whether the pesticide meets the "no unreasonable adverse effects" criterion of FIFRA.

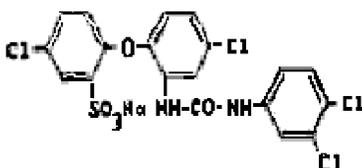
This document presents the Agency's decision regarding the reregistration eligibility of the registered uses of Mitin FF. The document consists of six sections. Section I is the introduction. Section II describes Mitin FF, its uses, data requirements and regulatory history. Section III discusses the human health and environmental assessment based on the data available to the Agency. Section IV presents the reregistration decision for Mitin FF. Section V discusses the reregistration requirements for Mitin FF. Finally, Section VI is the Appendices which support this Reregistration Eligibility Decision. Additional details concerning the Agency's review of applicable data are available on request.

## II. CASE OVERVIEW

### A. Chemical Overview

The following active ingredient is covered by this Reregistration Eligibility Decision:

- **Common Name:** Mitin FF
- **Chemical Name:** Sodium 5-chloro-2-(4-chloro-2- [(3,4-dichlorophenyl)ureido] phenoxy) benzenesulfonate
- **CAS Registry Number:** 3567-25-7
- **OPP Chemical Code:** 58802
- **Structural formula:**



- **Trade and Other Names:** Mitin FF
- **Basic Manufacturer:** Ciba-Geigy Corporation

### B. Use Profile

The following is information on the currently registered use with an overview of use sites and application methods. A detailed table of this use of **Mitin FF** is in Appendix A.

Mitin FF is used to moth-proof wool. It is supplied to the textile industry as an 80 percent active ingredient formulated fine powder. It is mixed into an aqueous solution by dissolving the powder in boiling water, and applied to wool during the dyeing/manufacturing process.

**Type of Pesticide:** Moth-proofing of wool

**Use Sites:** Textile Manufacture

**Target Pests:** Moth larvae

**Formulation**

**Types Registered:** Wettable powder

**Method and Rates of Application:**

Equipment Added to dyebath for textile to be treated

Method and Rate Use 1 to 1.5% Mitin FF (80%) calculated on the dry weight of the wool to be treated. Dissolve Mitin FF separately in the proportion of one pound Mitin (80%) to 5 gallons of water.

**C. Data Requirements**

The Agency required data to support reregistration through a Data Call-In (10/27/92) for Mitin FF during Phase IV of reregistration. Requirements included studies on ecological effects, product chemistry, environmental fate, and toxicology. These data were required to assess the potential risk from use identified on the current label. Appendix B includes all data requirements, identified by the Agency for currently registered uses, needed to support reregistration.

**D. Regulatory History**

The first and only pesticide product containing Mitin FF as an active ingredient was registered in 1948. Currently, there is one registered manufacturing-use/ end-use product. In 1992 the Agency issued a Data Call-in requiring the registrant to provide appropriate data described above for this active ingredient to support reregistration.

**III. SCIENCE ASSESSMENT**

Below is a summary of physical and chemical properties of Mitin FF. The specific studies reviewed for guidelines 61-1 through 63-13 are referenced in Appendix B.

**A. Physical Chemistry Assessment**

Color:	White
Physical State	Powder
Melting Point	208°C -decomposes during melting.
Density	1690 kg/cubic meter
Solubility	2% in water at 100°C
Vapor Pressure	1.9 X 10 <sup>-9</sup> Pascal
Octanol/Water Partition Coefficient	78.51 +/- 10.6
pH	7.46
Stability	Decomposes during melting

**B. Human Health Assessment**

**1. Toxicology Assessment**

The toxicology data base for Mitin FF is adequate for reregistration eligibility. Toxicology studies indicate that Mitin FF (80%) has moderate (oral) to low acute toxicity and that there are no toxicological characteristics associated with this active ingredient that lead to significant concerns.

**a. Acute Toxicity**

**Table 1 MAMMALIAN ACUTE TOXICITY**

TEST	RESULTS	CATEGORY
Oral LD50-- rats	849 mg/kg (♂); 476 mg/kg (♀); 645 mg/kg (♂ & ♀)	II
Dermal LD50--rats	> 2000 mg/kg (♂ & ♀)	III
Inhalation LC50--rats	> 4.82 mg/L	IV
Eye irritation--rabbits*	Slight to moderate, transient ocular irritation clearing in 14 days.	III
Dermal irritation--rabbits*	non-irritating	IV
Dermal sensitization--guinea pigs*	non-sensitizer	--

\* This study is a requirement for manufacturing-use and end-use products (40 CFR 158). The Mitin FF data have been generated for the TGAI and are presented here for informational purposes.

All acute toxicity studies performed with Mitin FF (a.i. 80%) are acceptable and fulfill the guideline requirements. The clinical signs of

toxicity most commonly seen in these studies were sedation, ruffled fur, hunched posture and uncoordinated movements. The estimated acute oral LD<sub>50</sub> for Mitin FF in both sexes of rats was 645 mg/kg (LD<sub>50</sub> for males = 849 mg/kg; LD<sub>50</sub> for females = 476 mg/kg), placing Mitin FF in toxicity category II (guideline 81-1; MRID 42249401). In an acute dermal toxicity study, the LD<sub>50</sub> for Mitin FF was > 2000 mg/kg b.w. for both sexes, placing Mitin FF in toxicity category III (guideline 81-2; MRID 42249402). The 4-hour inhalation LC<sub>50</sub> in both sexes of rats was 4.82 mg/L, placing Mitin FF in toxicity category III (guideline 81-3; MRID 42249403).

In a primary eye irritation study in rabbits, Mitin FF produced slight to moderate, transient ocular irritation. This cleared in 14 days (guideline 81-4; MRID 42249404). Mitin FF, in a primary dermal irritation study with ChbbIbm: NZW (SPF) rabbits, produced no skin irritation. Therefore, it was placed in category IV (guideline 81-5; MRID 42249405). In a dermal sensitization study, Mitin FF was tested with female guinea pigs and it was found to be a non-sensitizer (guideline 81-6; MRID 42249406).

#### **b. Subchronic Toxicity**

In a 90-day dermal toxicity study, Mitin FF was administered in doses of 0, 10, 100, or 1000 mg/kg/day to Wistar/HAN rats. The systemic toxicity LOEL in both sexes was >1000 mg/kg/day because the observed effects (marginal increase in body weight gain, and elevated total plasma bilirubin levels) were not biologically significant. The NOEL for systemic toxicity was ≥1000 mg/kg/day. The dermal toxicity LOEL was 1000 mg/kg/day based on increased incidence of general, patchy, and focal erythema, scaling and necrosis of the skin in both sexes. The NOEL for dermal toxicity was 100 mg/kg/day. The study (guideline 82-3; MRID 41595001) was acceptable as Core-minimum data.

#### **c. Chronic Toxicity/Carcinogenicity**

As this is a non-food use chemical, chronic toxicity and carcinogenicity studies are only triggered if the subchronic studies indicate NOELs of concern, and/or exposure is determined to be chronic in nature. Thus the Agency has not required these studies for Mitin FF.

**d. Developmental Toxicity**

In a developmental toxicity study, Mitin FF Technical was administered at doses 0, 5, 20, or 80 mg/kg by gavage to Wistar/HAN rats on gestation days 6 through 15, inclusive. The maternal toxicity NOEL is greater than or equal to 80mg/kg/day and the study was classified as unacceptable and non-upgradable because of failure to achieve significant maternal toxicity at 80 mg/kg/day. The developmental toxicity NOEL was >80 mg/kg/day and the LOEL was >80 mg/kg/day (guideline 83-3a; MRID 41157501).

In a developmental toxicity study in Russian Chbb.HM rabbits, Mitin FF was administered by gavage during gestation days 7-19 (inclusive) at dose levels of 0, 2, 6, 18, or 36 mg/kg/day. The maternal toxicity LOEL was 36 mg/kg/day (HDT) based on increased incidence of mortality (9 of 18 does) and clinical signs of toxicity. The maternal NOEL was 18 mg/kg/day. No developmental toxicity was noted at the dose levels tested. Therefore, the developmental LOEL was >36 mg/kg/day. The developmental NOEL was  $\geq$ 36 mg/kg/day. The study (guideline 83-3b; MRID 43465101) was acceptable as Core-minimum data.

**e. Mutagenicity**

All three mutagenicity assays were negative. In a reverse gene mutation assay using strains of *Salmonella typhimurium* (TA1535, TA1537, TA1538, TA98, and TA100) Mitin FF was negative up to cytotoxic levels (guideline 84-2a; MRID 41050901). In mouse micronucleus test (guideline 84-4; MRID 41027801) and rat hepatocyte UDS assay (guideline 84-4; MRID 41027802), no chromosomal aberrations or DNA damage were detected up to cytotoxic levels. These studies are acceptable and fulfill guidelines 84-2a and 84-4.

**f. Metabolism**

A metabolism study is not required to support non-food uses of Mitin FF because of the expected absence of oral exposure.

**g. Other Toxic Endpoints(Less Than Lifetime)**

The Office of Pesticide Programs (OPP) Less Than Lifetime Committee concluded (11/7/95) that since Mitin FF is a non-food chemical an acute dietary risk assessment was not required.

No quantitative risk assessment is needed for short-term (1 to 7 days), intermediate-term (1 week to several months), or chronic (several months to lifetime) occupational or residential exposure for the following reasons:

- 1) No systemic toxicity was observed in a 90-day dermal toxicity study in rats at the highest dose tested (1000 mg/kg/day).
- 2) No developmental effects were observed in a rat developmental study at the highest dose tested (80 mg/kg/day) or in a rabbit developmental study at the highest dose tested (36 mg/kg/day). The rat developmental study was classified as unacceptable due to the failure to achieve maternal toxicity at 80 mg/kg/day; however, the rabbit study was deemed acceptable (maternal toxicity LOEL = 36 mg/kg/day).

These studies, considered together, indicate that dermal absorption and, thus, systemic exposure to Mitin FF is minimal.

#### **h. Reference Dose**

The OPP RfD/QA Peer Review Committee recommended (10/19/95) not to establish a reference dose because of the non-food use patterns and exposure profile for this chemical. At this time the Joint FAO/WHO meeting on Pesticide Residues has not considered Mitin FF.

## **2. Exposure Assessment**

### **a. Occupational and Residential**

An occupational and/or residential exposure assessment is required for an active ingredient if (1) certain toxicological criteria are triggered and (2) there is potential exposure to handlers (mixers, loaders, applicators, etc.) during use or to persons entering treated sites after application is complete (i.e, factory workers exposed to Mitin FF residue after treatment of wool and the public exposed to residue on treated textile).

#### **Occupational-use products and homeowner-use products**

At this time no products containing Mitin FF are intended for homeowner use. All products containing Mitin FF are intended for occupational use.

## Handler Exposures

EPA has determined that there is a potential exposure to handlers during usual use-patterns associated with Mitin FF. There are potential exposures to mixers/loaders preparing aqueous solutions of Mitin FF and to applicators treating textiles with the prepared solution, and processing the treated textiles.

Based on the use pattern and potential exposures described above, The Agency has identified four major exposure scenarios for Mitin FF related to this application: (1) weighing the formulation; (2) mixing/loading the concentrated formulation into dyeing vats; (3) applying the formulation to textiles; and (4) processing the treated textiles.

One chemical-specific handler exposure study has been submitted to EPA in support of the Mitin FF reregistration (MRID 43498001, K.A. Hostetler). Estimation of Potential Consumer and Worker Exposure to Mitin FF (Revised). This study estimated potential consumer exposure (dermal) and occupational exposure (inhalation only) to Mitin FF. The study indicated that there is not significant inhalation or dermal exposure. Inhalation exposure to handlers of Mitin FF is unlikely due to the low vapor pressure ( $1.4 \times 10^{-8}$  mm Hg or  $1.9 \times 10^{-9}$  KPa).

## Post-Application Exposure

EPA has determined that there are potential post-application exposures. Workers handle the treated textiles and the general public come in contact with woolen products (e.g. clothes and carpets) made from the treated textiles. Except for the above referenced study on exposure, post-application exposure and residue dissipation data have not been submitted to EPA in support of the Mitin FF reregistration and are not required since there are no identified toxicological endpoints of concern and the above cited consumer and worker exposure study indicates low exposure.

**3. Risk Assessment**

**a. Occupational and Residential**

**Risk From Handler Exposures**

The Agency believes that the handler exposures associated with the application of the Mitin FF product will not pose an adverse risk to workers. There is no identified toxicological endpoint of concern and the worker exposure (inhalation) is assumed to be low.

**Risk From Post-Application Exposures**

The Agency believes that the risks from post-application exposures, as indicated in the above cited study, will not be adverse to the workers and the general public. Again, there is no identified toxicological endpoint of concern (for dermal exposure) and exposures are assumed to be low.

**C. Environmental Assessment**

**1. Ecological Toxicity Data**

The Agency requires only a limited set of ecotoxicology and environmental fate studies for industrial biocides. The data requirements for Mitin FF are fulfilled by studies submitted to the Agency. Based on review of these studies, Mitin FF is slightly toxic to birds, moderately to slightly toxic to mammals, and moderately toxic to fish and aquatic invertebrates.

**a. Toxicity to Terrestrial Animals**

An acute oral toxicity study using the technical grade of the active ingredient is required to establish the toxicity of a pesticide to birds. The preferred test species is either mallard duck or bobwhite quail. Results of this testing are tabulated below.

**Table 2 Avian Acute Oral Toxicity Findings**

Surrogate Species	% AI	LD <sub>50</sub> mg/kg ai (95% CL)	Toxicity Category	MRID No. Author/Year	Study Classification*
Northern Bobwhite <i>Colinus virginianus</i> (male and female)	84 %	801 (682 - 942)	slightly toxic	43273201 Helsten & Solatycki 1994	Core
Mallard Duck <i>Anas platyrhynchos</i> (male and female)	84 %	1,806 not applicable	slightly toxic	43273202 Helsten & Denk 1994	Core

\* Core=Acceptable (Study satisfies guidelines/Concur); S=Supplemental (Study provided useful information, but Guideline was not satisfied); N=Unacceptable (Study was rejected)/Nonconcur

The results for these formulations (84 % active ingredient) suggest that technical grade Mitin FF is slightly toxic to avian species on an acute oral basis. The guideline requirement (71-1) is fulfilled (MRID 43273201, 43273202).

One subacute dietary study using the technical grade of the active ingredient is required to establish the toxicity of a pesticide to birds. The preferred test species are mallard duck (a waterfowl) or bobwhite quail (an upland gamebird). Results of this testing are tabulated below.

**Table 3 Avian Subacute Dietary Findings**

Surrogate Species	% AI	LC <sub>50</sub> ppm ai (95% CL)	Toxicity Category	MRID No. Author/Year	Study Classification
Northern Bobwhite <i>Colinus virginianus</i>	84 %	4,200 2,100 - infinity	slightly toxic	43273203 Helsten & Denk 1994	Core

The results for these formulations (84 % a.i.) suggest that technical grade Mitin FF is slightly toxic to avian species on a subacute basis. The guideline requirement (71-2) is fulfilled. (MRID 43273203).

**b. Toxicity to Aquatic Animals**

**(1) Acute Toxicity to Freshwater Fish**

One freshwater fish toxicity study using the technical grade of the active ingredient is required to establish the toxicity of a pesticide to fish. The preferred test species is rainbow trout (a coldwater fish) or bluegill sunfish (a warmwater fish). Results of these tests are tabulated below.

**Table 4 Freshwater Fish 96-Hour LC50 Toxicity Findings**

Surrogate Species	% AI	LC <sub>50</sub> ppm ai (95% CL)	Toxicity Category	MRID No. Author/Year	Study Classification
Bluegill Sunfish <i>Lepomis macrochirus</i> (static, measured)	83.4 %	4.8 (2.4 - 9.6)	moderately toxic	40098001 Mayer & Ellersieck 1986	Core
Fathead Minnow <i>Pimephales promelas</i> (static, measured)	83.4 %	6.1 (4.5 - 8.2)	moderately toxic	40098001 Mayer & Ellersieck 1986	Core
Rainbow Trout <i>Oncorhynchus mykiss</i> (static, measured)	80 %	6.8 (5.3 - 10.1)	moderately toxic	42720101 Grade, R. 1993	Core

These results suggest that technical grade Mitin FF is moderately toxic to coldwater and warmwater fish species in

formulations of 80% to 84% ai. The guideline requirement (72-1) is fulfilled (MRID 40098001, 42720101).

**(2) Acute Toxicity to Freshwater Invertebrates**

A freshwater aquatic invertebrate toxicity test using the technical grade of the active ingredient is required to establish the toxicity of a pesticide to invertebrates. The preferred test species is *Daphnia magna*. Results of this test are tabulated below.

**Table 5 Freshwater Invertebrate EC50/LC50 Toxicity Findings**

Surrogate Species	% AI	LC <sub>50</sub> ppm ai (95% CL)	Toxicity Category	MRID No. Author/Year	Study Classification
Waterflea <i>Daphnia magna</i> (static, nominal)	84 %	9.46 (7.89-11.34)	moderately toxic	42270102 Ellgehausen & Wuethrich 1987	Core

These results suggest that technical grade Mitin FF is moderately toxic to freshwater aquatic invertebrates for the formulation tested. The guideline requirement (72-2) is fulfilled. (MRID 42270102).

**2. Environmental Fate**

The only data requirement that applies to this chemical is hydrolysis, guideline (161-1). A hydrolysis study has been received and found to be acceptable.

The submitted study indicates that Mitin FF is stable to hydrolysis under the conditions of the study: [<sup>14</sup>C] Mitin FF was stable in pH 5, 7, and 9 buffered solutions when incubated in the dark at 25.0-25.1°C. Mitin FF was 97.2-97.8% of applied at all pHs immediately following treatment and 97.3-97.4% after 31 days. Two minor components were detected in all three solutions, accounting for not more than 2.4% of the chemical applied. These were not identified. Recoveries were acceptable at all test intervals. There was measurable <sup>14</sup>CO<sub>2</sub> after 31 days of incubation, accounting for not more than 2.16% of the applied (MRID 43503301).

**3. Exposure and Risk Characterization**

**a. Exposure and Risk to Nontarget Organisms**

The Agency requires only a limited set of ecotoxicology and environmental fate studies for industrial biocides. Mitin FF is slightly

toxic to birds, moderately to slightly toxic to mammals, and moderately toxic to fish and aquatic invertebrates and, it can be stable to hydrolysis. While the hazard to nontarget organisms from Mitin FF has been characterized, a risk assessment has not been conducted. The risks to aquatic environments from industrial effluent from this use are regulated under the NPDES permitting program of the Agency's Office of Water. All labels for Mitin FF must require that discharges to aquatic environments comply with an NPDES permit.

**b. Endangered Species**

The Agency does not anticipate any exposure of concern to endangered species of fish and wildlife, providing that the Mitin FF product is handled and applied as specified in the product labeling and that discharges to the environment comply with Federal disposal laws and NPDES permits.

**IV. RISK MANAGEMENT AND REREGISTRATION DECISION**

**A. Determination of Eligibility**

Section 4(g)(2)(A) of FIFRA calls for the Agency to determine, after submission of relevant data concerning an active ingredient, whether products containing the active ingredient are eligible for reregistration. The Agency has previously identified and required the submission of the generic (i.e. active ingredient specific) data required to support reregistration of the product containing Mitin FF as an active ingredient. The Agency has completed its review of these generic data and has determined that the data are sufficient to support reregistration of the product. Appendix B identifies the generic data requirements that the Agency reviewed as part of its determination of reregistration eligibility of Mitin FF and lists the submitted studies that the Agency found acceptable.

The data identified in Appendix B were sufficient to allow the Agency to assess the registered use of Mitin FF and to determine that Mitin FF can be used without resulting in unreasonable adverse effects to humans and the environment. The Agency therefore finds that the one product containing Mitin FF as the active ingredient is eligible for reregistration. The reregistration of this product is addressed in Section V of this document.

The Agency made its reregistration eligibility determination based upon the target data base required for reregistration, the current guidelines for conducting acceptable studies to generate such data, published scientific literature, etc. and the data identified in Appendix B. Although the Agency has found that all uses of Mitin

FF are eligible for reregistration, it should be understood that the Agency may take appropriate regulatory action, and/or require the submission of additional data to support the registration of products containing Mitin FF, if new information comes to the Agency's attention or if the data requirements for registration (or the guidelines for generating such data) change.

## **B. Determination of Eligibility Decision**

### **1. Eligibility Decision**

Based on the reviews of the generic data for the active ingredient Mitin FF, the Agency has sufficient information on the potential health effects of Mitin FF and on its potential for causing adverse effects in fish and wildlife and the environment. The Agency has determined that Mitin FF products, labeled and used as specified in this Reregistration Eligibility Decision, will not pose unreasonable risks or adverse effects to humans or the environment. Therefore, the Agency concludes that the product containing Mitin FF for all uses is eligible for reregistration.

More specifically the Agency bases its decision of eligibility on the following conclusions about Mitin FF, which have been presented above throughout the document.

- Mitin FF has use and therefore benefits in the protection of woolen textile from insect damage.
- The toxicology database, although limited in its scope, suggests Mitin FF has low mammalian toxicity. Technical Mitin FF has low acute and subchronic toxicities from dermal and inhalation exposure; developmental toxicology studies in two species were negative for developmental effects; and, Mitin FF did not cause mutagenic effects in a battery of studies.
- Exposures to workers and the general public are expected to be low based on available although limited data. This coupled with the lack of concern for toxicity leads the Agency to conclude that risks to humans are negligible.
- Mitin FF's acute toxicity to wildlife species is low to moderate.
- Potential environmental exposures from the current use are limited to those from industrial effluents. Any associated risks are controlled through the NPDES permitting program.

## 2. Eligible and Ineligible Uses

The Agency has determined that all uses of Mitin FF are eligible for reregistration.

### C. Labeling Rationale/Risk Mitigation Measures

#### Worker Protection

While the Agency has concluded the risk to applicators and other workers are negligible it is prudent to require a continuation of current minimal label precautions to afford product user protection from unnecessary exposure. These label requirements are specified below in section V and must be retained and/or added since there may be potential for application and post application exposure.

#### Personal Protective Equipment/Engineering Control for Handlers

Currently, there is no toxicological basis from Mitin FF per se, to impose requirements of personal protective equipment (PPE) or engineering controls for applicators and other workers. However, the acute toxicity of the current formulated end-use product and future products may be such that the requirements and use of PPE and/or engineering controls may be appropriate on a product-specific basis. This is described further below in Section V.

## V. ACTIONS REQUIRED OF REGISTRANTS

This section specifies the data requirements and responses necessary for the reregistration of both manufacturing-use and end-use products.

### A. Manufacturing-Use Products

#### 1. Additional Generic Data Requirements

The generic data base supporting the reregistration of Mitin FF for the above eligible use has been reviewed and determined to be complete. No additional generic data is required at this time.

#### 2. Labeling Requirements for Manufacturing-Use Products

To remain in compliance with FIFRA, manufacturing use product (MP) labeling must be revised to comply with all current EPA regulations, PR Notices and applicable policies. The MP labeling must bear the following statement under Directions for Use:

"Only for formulation into an Insecticide or the applicable term which describes the type of pesticide use for the following use by MP registrant."

An MP registrant may, at his/her discretion, add one of the following statements to an MP label under

"Directions for Use" to permit the reformulation of the product for a specific use or all additional uses supported by a formulator or user group:

- (a) "This product may be used to formulate products for specific use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."
- (b) "This product may be used to formulate products for any additional use(s) not listed on the MP label if the formulator, user group, or grower has complied with U.S. EPA submission requirements regarding support of such use(s)."

## **B. End-Use Products**

### **1. Additional Product-Specific Data Requirements**

Section 4(g)(2)(B) of FIFRA calls for the Agency to obtain any needed product-specific data regarding the pesticide after a determination of eligibility has been made. The product specific data requirements are listed in Appendix G, the Product Specific Data Call-In Notice.

Registrants must review previous data submissions to ensure that they meet current EPA acceptance criteria (Appendix F; Attachment E) and if not, commit to conduct new studies. If a registrant believes that previously submitted data meet current testing standards, then study MRID numbers should be cited according to the instructions in the Requirement Status and Registrants Response Form provided for each product.

## 2. Labeling Requirements for End-Use Products

### **PPE/Engineering Control Requirements**

EPA is not establishing active-ingredient-based minimum (baseline) PPE/engineering control requirements for Mitin FF end-use products that are intended primarily for occupational use.

Any necessary PPE for each Mitin FF occupational end-use product will be established on the basis of the end-use product's acute toxicity category.

NOTE: All end-use products are required to specify a long-sleeved shirt, long pants, socks and shoes as minimum work attire for all handlers. If the end-use product is classified as toxicity category I or II for eye irritation potential, protective eyewear is also required.

The personal protective equipment requirements must be placed on the end-use product labeling in the location specified in PR Notice 93-7, and the format and language of the PPE requirements must be the same as is specified in PR Notice 93-7.

### **Entry Restrictions**

For end-use products that contain Mitin FF the product labeling must be revised to remove entry restrictions on the current labeling. As discussed above there is no toxicological basis to impose entry restrictions of the current use of Mitin FF.

### **Other Labeling Requirements**

The Agency is requiring the following labeling statements to be located on all end-use products containing Mitin FF.

### **Application Restrictions**

"Do not apply this product in a way that will contact workers or other persons."

### **User Safety Recommendations**

- "Users should wash hands before eating, drinking, chewing gum, using tobacco, or using the toilet."

- "Users should remove clothing immediately if pesticide gets inside. Then wash thoroughly and put on clean clothing."

The labels and labeling of all products must comply with EPA's current regulations and requirements as specified in 40 CFR §156.10 and other applicable notices.

### **C. Existing Stocks**

Registrants may generally distribute and sell products bearing old labels/labeling for 26 months from the date of the issuance of this Reregistration Eligibility Decision (RED). Persons other than the registrant may generally distribute or sell such products for 50 months from the date of the issuance of this RED. However, existing stocks time frames will be established case-by-case, depending on the number of products involved, the number of label changes, and other factors. Refer to "Existing Stocks of Pesticide Products; Statement of Policy"; Federal Register, Volume 56, No. 123, June 26, 1991.

The Agency has determined that registrants may distribute and sell Mitin FF products bearing old labels/labeling for 26 months from the date of issuance of this RED. Persons other than the registrant may distribute or sell such products for 50 months from the date of the issuance of this RED. Registrants and persons other than registrants remain obligated to meet pre-existing Agency imposed label changes and existing stocks requirements applicable to products they sell or distribute.



## **VI. APPENDICES**







## **GUIDE TO APPENDIX B**

Appendix B contains listings of data requirements which support the reregistration for active ingredients within the case Mitin FF covered by this Reregistration Eligibility Decision Document. It contains generic data requirements that apply to Mitin FF in all products, including data requirements for which a "typical formulation" is the test substance.

The data table is organized in the following format:

1. **Data Requirement** (Column 1). The data requirements are listed in the order in which they appear in 40 CFR Part 158. the reference numbers accompanying each test refer to the test protocols set in the Pesticide Assessment Guidelines, which are available from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161 (703) 487-4650.

2. **Use Pattern** (Column 2). This column indicates the use patterns for which the data requirements apply. The following letter designations are used for the given use patterns:

A	Terrestrial food
B	Terrestrial feed
C	Terrestrial non-food
D	Aquatic food
E	Aquatic non-food outdoor
F	Aquatic non-food industrial
G	Aquatic non-food residential
H	Greenhouse food
I	Greenhouse non-food
J	Forestry
K	Residential
L	Indoor food
M	Indoor non-food
N	Indoor medical
O	Indoor residential

3. **Bibliographic citation** (Column 3). If the Agency has acceptable data in its files, this column lists the identifying number of each study. This normally is the Master Record Identification (MRID) number, but may be a "GS" number if no MRID number has been assigned. Refer to the Bibliography appendix for a complete citation of the study.



# APPENDIX B

## Data Supporting Guideline Requirements for the Reregistration of Mitin FF

REQUIREMENT	USE PATTERN	CITATION(S)	
<b><u>PRODUCT CHEMISTRY</u></b>			
62-1	Preliminary Analysis	All	42357001
62-2	Certification of limits	All	42357001
62-3	Analytical Method	All	43174201
63-2	Color	All	42270101
63-3	Physical State	All	42270101
63-4	Odor	All	42270101
63-5	Melting Point	All	42270101
63-6	Boiling Point	All	42270101
63-7	Density	All	42270101
63-8	Solubility	All	42270101
63-9	Vapor Pressure	All	42270101
63-10	Dissociation Constant	All	42270101
63-11	Octanol/Water Partition	All	42270101
<b><u>ECOLOGICAL EFFECTS</u></b>			
71-1A	Acute Avian Oral - Quail/Duck	All	43273201, 43273202
71-1B	Acute Avian Oral - Quail/Duck TEP	All	43273201, 43273202
71-2A	Avian Dietary - Quail	All	40098001, 42720101
71-2B	Avian Dietary - Duck	All	42270102

## **Data Supporting Guideline Requirements for the Reregistration of Mitin FF**

<b>REQUIREMENT</b>	<b>USE PATTERN</b>	<b>CITATION(S)</b>
<b><u>TOXICOLOGY</u></b>		
<b>81-1</b>	<b>Acute Oral Toxicity - Rat</b>	All 42249401
<b>81-2</b>	<b>Acute Dermal Toxicity - Rabbit/Rat</b>	All 42249402
<b>81-3</b>	<b>Acute Inhalation Toxicity Rat</b>	42249403
<b>81-4</b>	<b>Primary Eye Irritation - Rabbit</b>	All 42249404
<b>81-5</b>	<b>Primary Dermal Irritation Rabbit</b>	All 42249405
<b>81-6</b>	<b>Dermal Sensitization Guinea Pig</b>	All 42249406
<b>82-3</b>	<b>90-Day Dermal - Rodent</b>	All 41595001
<b>83-3B</b>	<b>Developmental Toxicity - Rabbit</b>	All 43465101
<b>84-2A</b>	<b>Gene Mutation (Ames Test)</b>	All 41050901
<b>84-4</b>	<b>Other Genotoxic Effects</b>	All 41027801, 41027802
<b><u>ENVIRONMENTAL FATE</u></b>		
<b>161-1</b>	<b>Hydrolysis</b>	All 43503301

## GUIDE TO APPENDIX C

1. **CONTENTS OF BIBLIOGRAPHY.** This bibliography contains citations of all studies considered relevant by EPA in arriving at the positions and conclusions stated elsewhere in the Reregistration Eligibility Document. Primary sources for studies in this bibliography have been the body of data submitted to EPA and its predecessor agencies in support of past regulatory decisions. Selections from other sources including the published literature, in those instances where they have been considered, are included.
2. **UNITS OF ENTRY.** The unit of entry in this bibliography is called a "study". In the case of published materials, this corresponds closely to an article. In the case of unpublished materials submitted to the Agency, the Agency has sought to identify documents at a level parallel to the published article from within the typically larger volumes in which they were submitted. The resulting "studies" generally have a distinct title (or at least a single subject), can stand alone for purposes of review and can be described with a conventional bibliographic citation. The Agency has also attempted to unite basic documents and commentaries upon them, treating them as a single study.
3. **IDENTIFICATION OF ENTRIES.** The entries in this bibliography are sorted numerically by Master Record Identifier, or "MRID number". This number is unique to the citation, and should be used whenever a specific reference is required. It is not related to the six-digit "Accession Number" which has been used to identify volumes of submitted studies (see paragraph 4(d)(4) below for further explanation). In a few cases, entries added to the bibliography late in the review may be preceded by a nine character temporary identifier. These entries are listed after all MRID entries. This temporary identifying number is also to be used whenever specific reference is needed.
4. **FORM OF ENTRY.** In addition to the Master Record Identifier (MRID), each entry consists of a citation containing standard elements followed, in the case of material submitted to EPA, by a description of the earliest known submission. Bibliographic conventions used reflect the standard of the American National Standards Institute (ANSI), expanded to provide for certain special needs.
  - a. **Author.** Whenever the author could confidently be identified, the Agency has chosen to show a personal author. When no individual was identified, the Agency has shown an identifiable laboratory or testing facility as the author. When no author or laboratory could be identified, the Agency has shown the first submitter as the author.
  - b. **Document date.** The date of the study is taken directly from the document. When the date is followed by a question mark, the bibliographer has deduced the date from the evidence contained in the document. When the date appears

as (19??), the Agency was unable to determine or estimate the date of the document.

- c. **Title.** In some cases, it has been necessary for the Agency bibliographers to create or enhance a document title. Any such editorial insertions are contained between square brackets.
- d. **Trailing parentheses.** For studies submitted to the Agency in the past, the trailing parentheses include (in addition to any self-explanatory text) the following elements describing the earliest known submission:
  - (1) **Submission date.** The date of the earliest known submission appears immediately following the word "received."
  - (2) **Administrative number.** The next element immediately following the word "under" is the registration number, experimental use permit number, petition number, or other administrative number associated with the earliest known submission.
  - (3) **Submitter.** The third element is the submitter. When authorship is defaulted to the submitter, this element is omitted.
  - (4) **Volume Identification (Accession Numbers).** The final element in the trailing parentheses identifies the EPA accession number of the volume in which the original submission of the study appears. The six-digit accession number follows the symbol "CDL," which stands for "Company Data Library." This accession number is in turn followed by an alphabetic suffix which shows the relative position of the study within the volume.

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- 41027802 Uhl, S. (1988) Unscheduled DNA Synthesis in Primary Hepatocytes of Male Rats in vitro with Fat 81,011/J (Mitin FF High Conc): Proj. No. 133435. Unpublished study prepared by Cytotest Cell Research GmbH & Co. KG. 28 p.
- 41050901 Uhl, S. (1988) Salmonella Typhimurium Reverse Mutation Assay with Fat 81,011/J & Mitin FF High Conc.\*: CCR Project: 133413. Unpublished study prepared by Cytotest Cell Research. 36 p.
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- 42249402 Ullmann, L.; Althaus, P.; and; Hoff, N. (1991) Acute Dermal Toxicity Study with Fat 81,011/J in Rats: Mitin FF High Concentrate: Lab Project Number: 289517. Unpublished study prepared by RCC, Research and Consulting Co. A. G. 35 p.
- 42249403 Duchosal, F. (1990) 4-hour, Acute Inhalation Toxicity Study with Fat 81,011/J in Rats: Mitin FF High Concentrate: Lab Project Number: 289438. Unpublished study prepared by RCC, Research and Consulting Co. A. G. 44 p.
- 42249404 Ullmann, L.; Lucini, P.; and Hoff, N. (1991) Primary Eye Irritation Study with Fat 81,011/J in Rabbits: Mitin FF High Concentrate: Lab Project Number: 289528. Unpublished study prepared by RCC, Research and Consulting Company A. G. 33 p.

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- 43273201 Helsten, B.; Solatycki, A. (1994) 21-Day Acute Oral LC50 Study with Sample S9318TC (Mitin FF High Conc.) in Bobwhite Quail: Lab Project Number: 102-026-03. Unpublished study prepared by Bio-Life Assoc., Ltd. 55 p.
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# UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

WASHINGTON, D.C. 20460

OFFICE OF  
PREVENTION, PESTICIDES  
AND TOXIC SUBSTANCES

## DATA CALL-IN NOTICE

### CERTIFIED MAIL

Dear Sir or Madam:

This Notice requires you and other registrants of pesticide products containing the active ingredient identified in Attachment 1 of this Notice, the Data Call-In Chemical Status Sheet, to submit certain product specific data as noted herein to the U.S. Environmental Protection Agency (EPA, the Agency). These data are necessary to maintain the continued registration of your product(s) containing this active ingredient. Within 90 days after you receive this Notice you must respond as set forth in Section III below. Your response must state:

1. How you will comply with the requirements set forth in this Notice and its Attachments 1 through 6; or
2. Why you believe you are exempt from the requirements listed in this Notice and in Attachment 3, Requirements Status and Registrant's Response Form, (see section III-B); or
3. Why you believe EPA should not require your submission of product specific data in the manner specified by this Notice (see section III-D).

If you do not respond to this Notice, or if you do not satisfy EPA that you will comply with its requirements or should be exempt or excused from doing so, then the registration of your product(s) subject to this Notice will be subject to suspension. We have provided a list of all of your products subject to this Notice in Attachment 2, Data Call-In Response Form, as well as a list of all registrants who were sent this Notice (Attachment 6).

The authority for this Notice is section 3(c)(2)(B) of the Federal Insecticide, Fungicide and Rodenticide Act as amended (FIFRA), 7 U.S.C. section 136a(c)(2)(B). Collection of this information is authorized under the Paperwork Reduction Act by OMB Approval No. 2070-0107 and 2070-0057 (expiration date 03-31-96).

This Notice is divided into six sections and six Attachments. The Notice itself contains information and instructions applicable to all Data Call-In Notices. The Attachments contain specific chemical information and instructions. The six sections of the Notice are:

- Section I - Why You Are Receiving This Notice
- Section II - Data Required By This Notice
- Section III - Compliance With Requirements Of This Notice
- Section IV - Consequences Of Failure To Comply With This Notice
- Section V - Registrants' Obligation To Report Possible Unreasonable Adverse Effects
- Section VI - Inquiries And Responses To This Notice

The Attachments to this Notice are:

- 1 - Data Call-In Chemical Status Sheet
- 2 - Product-Specific Data Call-In Response Form
- 3 - Requirements Status and Registrant's Response Form
- 4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
- 5 - List of Registrants Receiving This Notice
- 6 - Cost Share and Data Compensation Forms

## SECTION I. WHY YOU ARE RECEIVING THIS NOTICE

The Agency has reviewed existing data for this active ingredient and reevaluated the data needed to support continued registration of the subject active ingredient. The Agency has concluded that the only additional data necessary are product specific data. No additional generic data requirements are being imposed. You have been sent this Notice because you have product(s) containing the subject active ingredient.

## SECTION II. DATA REQUIRED BY THIS NOTICE

### II-A. DATA REQUIRED

The product specific data required by this Notice are specified in Attachment 3, Requirements Status and Registrant's Response Form. Depending on the results of the studies required in this Notice, additional testing may be required.

### II-B. SCHEDULE FOR SUBMISSION OF DATA

You are required to submit the data or otherwise satisfy the data requirements specified in Attachment 3, Requirements Status and Registrant's Response Form, within the time frames provided.

### II-C. TESTING PROTOCOL

All studies required under this Notice must be conducted in accordance with test standards outlined in the Pesticide Assessment Guidelines for those studies for which guidelines have been established.

These EPA Guidelines are available from the National Technical Information Service (NTIS), Attn: Order Desk, 5285 Port Royal Road, Springfield, Va 22161 (tel: 703-487-4650).

Protocols approved by the Organization for Economic Cooperation and Development (OECD) are also acceptable if the OECD-recommended test standards conform to those specified in the Pesticide Data Requirements regulation (40 CFR § 158.70). When using the OECD protocols, they should be modified as appropriate so that the data generated by the study will satisfy the requirements of 40 CFR § 158. Normally, the Agency will not extend deadlines for complying with data requirements when the studies were not conducted in accordance with acceptable standards. The OECD protocols are available from OECD, 2001 L Street, N.W., Washington, D.C. 20036 (Telephone number 202-785-6323; Fax telephone number 202-785-0350).

All new studies and proposed protocols submitted in response to this Data Call-In Notice must be in accordance with Good Laboratory Practices [40 CFR Part 160.3(a)(6)].

#### II-D. REGISTRANTS RECEIVING PREVIOUS SECTION 3(c)(2)(B) NOTICES ISSUED BY THE AGENCY

Unless otherwise noted herein, this Data Call-In does not in any way supersede or change the requirements of any previous Data Call-In(s), or any other agreements entered into with the Agency pertaining to such prior Notice. Registrants must comply with the requirements of all Notices to avoid issuance of a Notice of Intent to Suspend their affected products.

### SECTION III. COMPLIANCE WITH REQUIREMENTS OF THIS NOTICE

#### III-A. SCHEDULE FOR RESPONDING TO THE AGENCY

The appropriate responses initially required by this Notice for product specific data must be submitted to the Agency within 90 days after your receipt of this Notice. Failure to adequately respond to this Notice within 90 days of your receipt will be a basis for issuing a Notice of Intent to Suspend (NOIS) affecting your products. This and other bases for issuance of NOIS due to failure to comply with this Notice are presented in Section IV-A and IV-B.

#### III-B. OPTIONS FOR RESPONDING TO THE AGENCY

The options for responding to this Notice for product specific data are: (a) voluntary cancellation, (b) agree to satisfy the product specific data requirements imposed by this notice or (c) request a data waiver(s).

A discussion of how to respond if you chose the Voluntary Cancellation option is presented below. A discussion of the various options available for satisfying the product specific

data requirements of this Notice is contained in Section III-C. A discussion of options relating to requests for data waivers is contained in Section III-D.

There are two forms that accompany this Notice of which, depending upon your response, one or both must be used in your response to the Agency. These forms are the Data-Call-In Response Form, and the Requirements Status and Registrant's Response Form, Attachment 2 and Attachment 3. The Data Call-In Response Form must be submitted as part of every response to this Notice. In addition, one copy of the Requirements Status and Registrant's Response Form must be submitted for each product listed on the Data Call-In Response Form unless the voluntary cancellation option is selected or unless the product is identical to another (refer to the instructions for completing the Data Call-In Response Form in Attachment 2). Please note that the company's authorized representative is required to sign the first page of the Data Call-In Response Form and Requirements Status and Registrant's Response Form (if this form is required) and initial any subsequent pages. The forms contain separate detailed instructions on the response options. Do not alter the printed material. If you have questions or need assistance in preparing your response, call or write the contact person(s) identified in Attachment 1.

1. Voluntary Cancellation - You may avoid the requirements of this Notice by requesting voluntary cancellation of your product(s) containing the active ingredient that is the subject of this Notice. If you wish to voluntarily cancel your product, you must submit a completed Data Call-In Response Form, indicating your election of this option. Voluntary cancellation is item number 5 on the Data Call-In Response Form. If you choose this option, this is the only form that you are required to complete.

If you chose to voluntarily cancel your product, further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provisions of this Notice which are contained in Section IV-C.

2. Satisfying the Product Specific Data Requirements of this Notice There are various options available to satisfy the product specific data requirements of this Notice. These options are discussed in Section III-C of this Notice and comprise options 1 through 6 on the Requirements Status and Registrant's Response Form and item numbers 7a and 7b on the Data Call-In Response Form. Deletion of a use(s) and the low volume/minor use option are not valid options for fulfilling product specific data requirements.

3. Request for Product Specific Data Waivers. Waivers for product specific data are discussed in Section III-D of this Notice and are covered by option 7 on the Requirements Status and Registrant's Response Form. If you choose one of these options, you must submit both forms as well as any other information/data pertaining to the option chosen to address the data requirement.

### III-C SATISFYING THE DATA REQUIREMENTS OF THIS NOTICE

If you acknowledge on the Data Call-In Response Form that you agree to satisfy the product specific data requirements (i.e. you select item number 7a or 7b), then you must select one of the six options on the Requirements Status and Registrant's Response Form related to data production for each data requirement. Your option selection should be entered under item

number 9, "Registrant Response." The six options related to data production are the first six options discussed under item 9 in the instructions for completing the Requirements Status and Registrant's Response Form. These six options are listed immediately below with information in parentheses to guide registrants to additional instructions provided in this Section. The options are:

- (1) I will generate and submit data within the specified time frame (Developing Data)
- (2) I have entered into an agreement with one or more registrants to develop data jointly (Cost Sharing)
- (3) I have made offers to cost-share (Offers to Cost Share)
- (4) I am submitting an existing study that has not been submitted previously to the Agency by anyone (Submitting an Existing Study)
- (5) I am submitting or citing data to upgrade a study classified by EPA as partially acceptable and upgradeable (Upgrading a Study)
- (6) I am citing an existing study that EPA has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (Citing an Existing Study)

Option 1, Developing Data -- If you choose to develop the required data it must be in conformance with Agency deadlines and with other Agency requirements as referenced herein and in the attachments. All data generated and submitted must comply with the Good Laboratory Practice (GLP) rule (40 CFR Part 160), be conducted according to the Pesticide Assessment Guidelines (PAG), and be in conformance with the requirements of PR Notice 86-5.

The time frames in the Requirements Status and Registrant's Response Form are the time frames that the Agency is allowing for the submission of completed study reports. The noted deadlines run from the date of the receipt of this Notice by the registrant. If the data are not submitted by the deadline, each registrant is subject to receipt of a Notice of Intent to Suspend the affected registration(s).

If you cannot submit the data/reports to the Agency in the time required by this Notice and intend to seek additional time to meet the requirements(s), you must submit a request to the Agency which includes: (1) a detailed description of the expected difficulty and (2) a proposed schedule including alternative dates for meeting such requirements on a step-by-step basis. You must explain any technical or laboratory difficulties and provide documentation from the laboratory performing the testing. While EPA is considering your request, the original deadline remains. The Agency will respond to your request in writing. If EPA does not grant your request, the original deadline remains. Normally, extensions can be requested only in cases of extraordinary testing problems beyond the expectation or control of the registrant. Extensions will not be given in submitting the 90-day responses. Extensions will not be considered if the request for extension is not made in a timely fashion; in no event shall an extension request be considered if it is submitted at or after the lapse of the subject deadline.

Option 2, Agreement to Share in Cost to Develop Data -- Registrants may only choose this option for acute toxicity data and certain efficacy data and only if EPA has indicated in the attached data tables that your product and at least one other product are similar for purposes of depending on the same data. If this is the case, data may be generated for just one of the products

in the group. The registration number of the product for which data will be submitted must be noted in the agreement to cost share by the registrant selecting this option. If you choose to enter into an agreement to share in the cost of producing the required data but will not be submitting the data yourself, you must provide the name of the registrant who will be submitting the data. You must also provide EPA with documentary evidence that an agreement has been formed. Such evidence may be your letter offering to join in an agreement and the other registrant's acceptance of your offer, or a written statement by the parties that an agreement exists. The agreement to produce the data need not specify all of the terms of the final arrangement between the parties or the mechanism to resolve the terms. Section 3(c)(2)(B) provides that if the parties cannot resolve the terms of the agreement they may resolve their differences through binding arbitration.

Option 3, Offer to Share in the Cost of Data Development -- This option only applies to acute toxicity and certain efficacy data as described in option 2 above. If you have made an offer to pay in an attempt to enter into an agreement or amend an existing agreement to meet the requirements of this Notice and have been unsuccessful, you may request EPA (by selecting this option) to exercise its discretion not to suspend your registration(s), although you do not comply with the data submission requirements of this Notice. EPA has determined that as a general policy, absent other relevant considerations, it will not suspend the registration of a product of a registrant who has in good faith sought and continues to seek to enter into a joint data development/cost sharing program, but the other registrant(s) developing the data has refused to accept your offer. To qualify for this option, you must submit documentation to the Agency proving that you have made an offer to another registrant (who has an obligation to submit data) to share in the burden of developing that data. You must also submit to the Agency a completed EPA Form 8570-32, Certification of Offer to Cost Share in the Development of Data, Attachment 7. In addition, you must demonstrate that the other registrant to whom the offer was made has not accepted your offer to enter into a cost sharing agreement by including a copy of your offer and proof of the other registrant's receipt of that offer (such as a certified mail receipt). Your offer must, in addition to anything else, offer to share in the burden of producing the data upon terms to be agreed or failing agreement to be bound by binding arbitration as provided by FIFRA section 3(c)(2)(B)(iii) and must not qualify this offer. The other registrant must also inform EPA of its election of an option to develop and submit the data required by this Notice by submitting a Data Call-In Response Form and a Requirements Status and Registrant's Response Form committing to develop and submit the data required by this Notice.

In order for you to avoid suspension under this option, you may not withdraw your offer to share in the burdens of developing the data. In addition, the other registrant must fulfill its commitment to develop and submit the data as required by this Notice. If the other registrant fails to develop the data or for some other reason is subject to suspension, your registration as well as that of the other registrant will normally be subject to initiation of suspension proceedings, unless you commit to submit, and do submit the required data in the specified time frame. In such cases, the Agency generally will not grant a time extension for submitting the data.

Option 4, Submitting an Existing Study -- If you choose to submit an existing study in response to this Notice, you must determine that the study satisfies the requirements imposed by this Notice. You may only submit a study that has not been previously submitted to the Agency or previously cited by anyone. Existing studies are studies which predate issuance of this Notice. Do not use this option if you are submitting data to upgrade a study. (See Option 5).

You should be aware that if the Agency determines that the study is not acceptable, the Agency will require you to comply with this Notice, normally without an extension of the required date of submission. The Agency may determine at any time that a study is not valid and needs to be repeated.

To meet the requirements of the DCI Notice for submitting an existing study, all of the following three criteria must be clearly met:

- a. You must certify at the time that the existing study is submitted that the raw data and specimens from the study are available for audit and review and you must identify where they are available. This must be done in accordance with the requirements of the Good Laboratory Practice (GLP) regulation, 40 CFR Part 160. As stated in 40 CFR 160.3(j) " 'raw data' means any laboratory worksheets, records, memoranda, notes, or exact copies thereof, that are the result of original observations and activities of a study and are necessary for the reconstruction and evaluation of the report of that study. In the event that exact transcripts of raw data have been prepared (e.g., tapes which have been transcribed verbatim, dated, and verified accurate by signature), the exact copy or exact transcript may be substituted for the original source as raw data. 'Raw data' may include photographs, microfilm or microfiche copies, computer printouts, magnetic media, including dictated observations, and recorded data from automated instruments." The term "specimens", according to 40 CFR 160.3(k), means "any material derived from a test system for examination or analysis."
- b. Health and safety studies completed after May 1984 must also contain all GLP-required quality assurance and quality control information, pursuant to the requirements of 40 CFR Part 160. Registrants must also certify at the time of submitting the existing study that such GLP information is available for post-May 1984 studies by including an appropriate statement on or attached to the study signed by an authorized official or representative of the registrant.
- c. You must certify that each study fulfills the acceptance criteria for the Guideline relevant to the study provided in the FIFRA Accelerated Reregistration Phase 3 Technical Guidance and that the study has been conducted according to the Pesticide Assessment Guidelines (PAG) or meets the purpose of the PAG (both available from NTIS). A study not conducted according to the PAG may be submitted to the Agency for consideration if the registrant believes that the study clearly meets the purpose of the PAG. The registrant is referred to 40 CFR 158.70 which states the Agency's policy regarding acceptable protocols. If you wish to submit the study, you must, in addition to certifying that the purposes of the PAG are met by the study, clearly articulate the rationale why you believe the study meets the purpose of the PAG, including copies of any supporting information or data. It has been the Agency's experience that studies completed prior to January 1970 rarely satisfied the purpose of the PAG and that necessary raw data are usually not available for such studies.

If you submit an existing study, you must certify that the study meets all requirements of the criteria outlined above.

If you know of a study pertaining to any requirement in this Notice which does not meet the criteria outlined above but does contain factual information regarding unreasonable adverse effects, you must notify the Agency of such a study. If such study is in the Agency's files, you need only cite it along with the notification. If not in the Agency's files, you must submit a summary and copies as required by PR Notice 86-5.

Option 5, Upgrading a Study -- If a study has been classified as partially acceptable and upgradeable, you may submit data to upgrade that study. The Agency will review the data submitted and determine if the requirement is satisfied. If the Agency decides the requirement is not satisfied, you may still be required to submit new data normally without any time extension. Deficient, but upgradeable studies will normally be classified as supplemental. However, it is important to note that not all studies classified as supplemental are upgradeable. If you have questions regarding the classification of a study or whether a study may be upgraded, call or write the contact person listed in Attachment 1. If you submit data to upgrade an existing study you must satisfy or supply information to correct all deficiencies in the study identified by EPA. You must provide a clearly articulated rationale of how the deficiencies have been remedied or corrected and why the study should be rated as acceptable to EPA. Your submission must also specify the MRID number(s) of the study which you are attempting to upgrade and must be in conformance with PR Notice 86-5.

Do not submit additional data for the purpose of upgrading a study classified as unacceptable and determined by the Agency as not capable of being upgraded.

This option should also be used to cite data that has been previously submitted to upgrade a study, but has not yet been reviewed by the Agency. You must provide the MRID number of the data submission as well as the MRID number of the study being upgraded.

The criteria for submitting an existing study, as specified in Option 4 above, apply to all data submissions intended to upgrade studies. Additionally your submission of data intended to upgrade studies must be accompanied by a certification that you comply with each of those criteria as well as a certification regarding protocol compliance with Agency requirements.

Option 6, Citing Existing Studies -- If you choose to cite a study that has been previously submitted to EPA, that study must have been previously classified by EPA as acceptable or it must be a study which has not yet been reviewed by the Agency. Acceptable toxicology studies generally will have been classified as "core-guideline" or "core minimum." For all other disciplines the classification would be "acceptable." With respect to any studies for which you wish to select this option you must provide the MRID number of the study you are citing and, if the study has been reviewed by the Agency, you must provide the Agency's classification of the study.

If you are citing a study of which you are not the original data submitter, you must submit a completed copy of EPA Form 8570-31, Certification with Respect to Data Compensation Requirements.

Registrants who select one of the above 6 options must meet all of the requirements described in the instructions for completing the Data Call-In Response Form and the Requirements Status and Registrant's Response Form, as appropriate.

### III-D REQUESTS FOR DATA WAIVERS

If you request a waiver for product specific data because you believe it is inappropriate, you must attach a complete justification for the request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. (Note: any supplemental data must be submitted in the format required by PR Notice 86-5). This will be the only opportunity to state the reasons or provide information in support of your request. If the Agency approves your waiver request, you will not be required to supply the data pursuant to section 3(c)(2)(B) of FIFRA. If the Agency denies your waiver request, you must choose an option for meeting the data requirements of this Notice within 30 days of the receipt of the Agency's decision. You must indicate and submit the option chosen on the Requirements Status and Registrant's Response Form. Product specific data requirements for product chemistry, acute toxicity and efficacy (where appropriate) are required for all products and the Agency would grant a waiver only under extraordinary circumstances. You should also be aware that submitting a waiver request will not automatically extend the due date for the study in question. Waiver requests submitted without adequate supporting rationale will be denied and the original due date will remain in force.

## IV. CONSEQUENCES OF FAILURE TO COMPLY WITH THIS NOTICE

### IV-A NOTICE OF INTENT TO SUSPEND

The Agency may issue a Notice of Intent to Suspend products subject to this Notice due to failure by a registrant to comply with the requirements of this Data Call-In Notice, pursuant to FIFRA section 3(c)(2)(B). Events which may be the basis for issuance of a Notice of Intent to Suspend include, but are not limited to, the following:

1. Failure to respond as required by this Notice within 90 days of your receipt of this Notice.
2. Failure to submit on the required schedule an acceptable proposed or final protocol when such is required to be submitted to the Agency for review.
3. Failure to submit on the required schedule an adequate progress report on a study as required by this Notice.
4. Failure to submit on the required schedule acceptable data as required by this Notice.
5. Failure to take a required action or submit adequate information pertaining to any option chosen to address the data requirements (e.g., any required action or information pertaining to submission or citation of existing studies or offers, arrangements, or arbitration on the sharing of costs or the formation of Task

Forces, failure to comply with the terms of an agreement or arbitration concerning joint data development or failure to comply with any terms of a data waiver).

6. Failure to submit supportable certifications as to the conditions of submitted studies, as required by Section III-C of this Notice.
7. Withdrawal of an offer to share in the cost of developing required data.
8. Failure of the registrant to whom you have tendered an offer to share in the cost of developing data and provided proof of the registrant's receipt of such offer or failure of a registrant on whom you rely for a generic data exemption either to:
  - a. inform EPA of intent to develop and submit the data required by this Notice on a Data Call-In Response Form and a Requirements Status and Registrant's Response Form;
  - b. fulfill the commitment to develop and submit the data as required by this Notice; or
  - c. otherwise take appropriate steps to meet the requirements stated in this Notice, unless you commit to submit and do submit the required data in the specified time frame.
9. Failure to take any required or appropriate steps, not mentioned above, at any time following the issuance of this Notice.

#### IV-B. BASIS FOR DETERMINATION THAT SUBMITTED STUDY IS UNACCEPTABLE

The Agency may determine that a study (even if submitted within the required time) is unacceptable and constitutes a basis for issuance of a Notice of Intent to Suspend. The grounds for suspension include, but are not limited to, failure to meet any of the following:

1. EPA requirements specified in the Data Call-In Notice or other documents incorporated by reference (including, as applicable, EPA Pesticide Assessment Guidelines, Data Reporting Guidelines, and GeneTox Health Effects Test Guidelines) regarding the design, conduct, and reporting of required studies. Such requirements include, but are not limited to, those relating to test material, test procedures, selection of species, number of animals, sex and distribution of animals, dose and effect levels to be tested or attained, duration of test, and, as applicable, Good Laboratory Practices.
2. EPA requirements regarding the submission of protocols, including the incorporation of any changes required by the Agency following review.
3. EPA requirements regarding the reporting of data, including the manner of reporting, the completeness of results, and the adequacy of any required supporting (or raw) data, including, but not limited to, requirements referenced or included in this Notice or

contained in PR 86-5. All studies must be submitted in the form of a final report; a preliminary report will not be considered to fulfill the submission requirement.

#### IV-C EXISTING STOCKS OF SUSPENDED OR CANCELLED PRODUCTS

EPA has statutory authority to permit continued sale, distribution and use of existing stocks of a pesticide product which has been suspended or cancelled if doing so would be consistent with the purposes of the Act.

The Agency has determined that such disposition by registrants of existing stocks for a suspended registration when a section 3(c)(2)(B) data request is outstanding would generally not be consistent with the Act's purposes. Accordingly, the Agency anticipates granting registrants permission to sell, distribute, or use existing stocks of suspended product(s) only in exceptional circumstances. If you believe such disposition of existing stocks of your product(s) which may be suspended for failure to comply with this Notice should be permitted, you have the burden of clearly demonstrating to EPA that granting such permission would be consistent with the Act. You must also explain why an "existing stocks" provision is necessary, including a statement of the quantity of existing stocks and your estimate of the time required for their sale, distribution, and use. Unless you meet this burden the Agency will not consider any request pertaining to the continued sale, distribution, or use of your existing stocks after suspension.

If you request a voluntary cancellation of your product(s) as a response to this Notice and your product is in full compliance with all Agency requirements, you will have, under most circumstances, one year from the date your 90 day response to this Notice is due, to sell, distribute, or use existing stocks. Normally, the Agency will allow persons other than the registrant such as independent distributors, retailers and end users to sell, distribute or use such existing stocks until the stocks are exhausted. Any sale, distribution or use of stocks of voluntarily cancelled products containing an active ingredient for which the Agency has particular risk concerns will be determined on case-by-case basis.

Requests for voluntary cancellation received after the 90 day response period required by this Notice will not result in the Agency granting any additional time to sell, distribute, or use existing stocks beyond a year from the date the 90 day response was due unless you demonstrate to the Agency that you are in full compliance with all Agency requirements, including the requirements of this Notice. For example, if you decide to voluntarily cancel your registration six months before a 3 year study is scheduled to be submitted, all progress reports and other information necessary to establish that you have been conducting the study in an acceptable and good faith manner must have been submitted to the Agency, before EPA will consider granting an existing stocks provision.

#### SECTION V. REGISTRANTS' OBLIGATION TO REPORT POSSIBLE UNREASONABLE ADVERSE EFFECTS

Registrants are reminded that FIFRA section 6(a)(2) states that if at any time after a pesticide is registered a registrant has additional factual information regarding unreasonable adverse effects on the environment by the pesticide, the registrant shall submit the information to the Agency. Registrants must notify the Agency of any factual information they have, from

whatever source, including but not limited to interim or preliminary results of studies, regarding unreasonable adverse effects on man or the environment. This requirement continues as long as the products are registered by the Agency.

#### SECTION VI. INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding the requirements and procedures established by this Notice, call the contact person(s) listed in Attachment 1, the Data Call-In Chemical Status Sheet.

All responses to this Notice (other than voluntary cancellation requests and generic data exemption claims) must include a completed Data Call-In Response Form and a completed Requirements Status and Registrant's Response Form (Attachment 2 and Attachment 3 for product specific data) and any other documents required by this Notice, and should be submitted to the contact person(s) identified in Attachment 1. If the voluntary cancellation or generic data exemption option is chosen, only the Data Call-In Response Form need be submitted.

The Office of Compliance Monitoring (OCM) of the Office of Pesticides and Toxic Substances (OPTS), EPA, will be monitoring the data being generated in response to this Notice.

Sincerely yours,

Lois A. Rossi, Division Director  
Special Review and  
Reregistration Division

#### Attachments

- 1 - Data Call-In Chemical Status Sheet
- 2 - Product-Specific Data Call-In Response Form
- 3 - Requirements Status and Registrant's Response Form
- 4 - EPA Batching of End-Use Products for Meeting Acute Toxicology Data Requirements for Reregistration
- 5 - List of Registrants Receiving This Notice
- 6 - Cost Share and Data Compensation Forms and the Confidential Statement of Formula Form

## MITIN FF DATA CALL-IN CHEMICAL STATUS SHEET

### INTRODUCTION

You have been sent this Product Specific Data Call-In Notice because you have product(s) containing Mitin DD.

This Product Specific Data Call-In Chemical Status Sheet, contains an overview of data required by this notice, and point of contact for inquiries pertaining to the reregistration of Mitin FF. This attachment is to be used in conjunction with (1) the Product Specific Data Call-In Notice, (2) the Product Specific Data Call-In Response Form (Attachment 2), (3) the Requirements Status and Registrant's Form (Attachment 3), (4) EPA's Grouping of End-Use Products for Meeting Acute Toxicology Data Requirement (Attachment 4), (5) a list of registrants receiving this DCI (Attachment 5) and (6) the Cost Share and Data Compensation Forms in replying to this Mitin FF Product Specific Data Call-In (Attachment (6)). Instructions and guidance accompany each form.

### DATA REQUIRED BY THIS NOTICE

The additional data requirements needed to complete the database for Mitin FF are contained in the Requirements Status and Registrant's Response, Attachment 3. The Agency has concluded that additional data on Mitin FF are needed for specific products. These data are required to be submitted to the Agency within the time frame listed. These data are needed to fully complete the reregistration of all eligible Mitin FF products.

### INQUIRIES AND RESPONSES TO THIS NOTICE

If you have any questions regarding this product specific data requirements and procedures established by this Notice, please contact Jeffrey Billingslea at (703) 308-8004.

All responses to this Notice for the Product Specific data requirements should be submitted to:

Jeffrey Billingslea  
Chemical Review Manager Team 81  
Product Reregistration Branch  
Special Review and Reregistration Branch 7508W  
Office of Pesticide Programs  
U.S. Environmental Protection Agency  
Washington, D.C. 20460

RE: **Mitin FF**

INSTRUCTIONS FOR COMPLETING THE **DATA CALL-IN RESPONSE FORM** FOR  
**PRODUCT SPECIFIC DATA**

- Item 1-4. Already completed by EPA.
- Item 5. If you wish to **voluntarily cancel** your product, answer "**yes.**" If you choose this option, you will not have to provide the data required by the Data Call-In Notice and you will not have to complete any other forms. Further sale and distribution of your product after the effective date of cancellation must be in accordance with the Existing Stocks provision of the Data Call-In Notice (Section IV-C).
- Item 6. Not applicable since this form calls in product specific data only. However, if your product is **identical** to another product and you qualify for a **data exemption**, you must respond with "**yes**" to Item 7a (MUP) or 7B (EUP) on this form, provide the **EPA registration numbers of your source(s)** you would **not** complete the "Requirements Status and Registrant's Response" form. Examples of such products include **repackaged** products and **Special Local Needs (Section 24c)** products which are identical to federally registered products.
- Item 7a. For each **manufacturing use product** (MUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes.**"
- Item 7b. For each **end use product** (EUP) for which you wish to maintain registration, you must agree to satisfy the data requirements by responding "**yes.**" If you are requesting a **data waiver**, answer "**yes**" here; in addition, on the "Requirements Status and Registrant's Response" form under Item 9, you must respond with **Option 7** (Waiver Request) for each study for which you are requesting a waiver. See Item 6 with regard to identical products and data exemptions.
- Items 8-11. Self-explanatory.

**NOTE:** You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

**Part A of the Product Specific DCI is inserted here.**



INSTRUCTIONS FOR COMPLETING THE **REQUIREMENTS STATUS AND REGISTRANT'S RESPONSE FORM** FOR **PRODUCT SPECIFIC DATA**

- Item 1-3 Completed by EPA. Note the **unique identifier number** assigned by EPA in Item 3. This number **must be used in the transmittal document for any data submissions** in response to this Data Call-In Notice.
- Item 4. The guideline reference numbers of studies required to support the product's continued registration are identified. These guidelines, in addition to the requirements specified in the Notice, govern the conduct of the required studies. Note that series 61 and 62 in product chemistry are now listed under 40 CFR 158.155 through 158.180, Subpart C.
- Item 5. The study title associated with the guideline reference number is identified.
- Item 6. The use pattern(s) of the pesticide associated with the product specific requirements is (are) identified. For most product specific data requirements, all use patterns are covered by the data requirements. In the case of efficacy data, the required studies only pertain to products which have the use sites and/or pests indicated.
- Item 7. The substance to be tested is identified by EPA. For product specific data, the product as formulated for sale and distribution is the test substance, except in rare cases.
- Item 8. The due date for submission of each study is identified. It is normally based on **8 months after issuance of the Reregistration Eligibility Document** unless EPA determines that a longer time period is necessary.
- Item 9. **Enter only one of the following response codes for each data requirement to show how you intend to comply with the data requirements listed in this table.** Fuller descriptions of each option are contained in the Data Call-In Notice.
1. I will generate and submit data by the specified due date (**Developing Data**). By indicating that I have chosen this option, I certify that I will comply with all the requirements pertaining to the conditions for submittal of this study as outlined in the Data Call-In Notice. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" form (EPA Form 8570-29) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**
  2. I have entered into an agreement with one or more registrants to develop data jointly (**Cost Sharing**). I am submitting a **copy of this agreement**. I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Notice that my product is similar enough to another

product to qualify for this option. I certify that another party in the agreement is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" form EPA Form 8570-29) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**

3. I have made offers to share in the cost to develop data (**Offers to Cost Share**). I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if EPA indicates in an attachment to this Data Call-In Notice that my product is similar enough to another product to qualify for this option. I am submitting **evidence that I have made an offer** to another registrant (who has an obligation to submit data) to share in the cost of that data. I am also submitting a completed "**Certification of Offer to Cost Share in the Development Data**" form I am including a copy of my offer and proof of the other registrant's receipt of that offer. I am identifying the party which is committing to submit or provide the required data; if the required study is not submitted on time, my product may be subject to suspension. I understand that other terms under Option 3 in the Data Call-In Notice (Section III-C.1.) apply as well. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" form (EPA Form 8570-29) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**
4. By the specified due date, I will submit an existing study that has not been submitted previously to the Agency by anyone (**Submitting an Existing Study**). I certify that this study will meet all the requirements for submittal of existing data outlined in Option 4 in the Data Call-In Notice (Section III-C.1.) and will meet the attached acceptance criteria (for acute toxicity and product chemistry data). I will attach the needed supporting information along with this response. I also certify that I have determined that this study will fill the data requirement for which I have indicated this choice. By the specified due date, I will also submit a completed "**Certification With Respect To Data Compensation Requirements**" form (EPA Form 8570-29) to show what data compensation option I have chosen. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" form EPA Form 8570-29) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**
5. By the specified due date, I will submit or cite data to upgrade a study classified by the Agency as partially acceptable and upgradable (**Upgrading a Study**). I will submit **evidence of the Agency's review** indicating that the study may be upgraded and what information is required to do so. I will provide the MRID or Accession number of the study at the due date. I understand that the conditions for this option outlined Option 5 in the Data Call-In Notice (Section III-C.1.) apply. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" form (EPA Form 8570-29) and (2) two

completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

6. By the specified due date, I will cite an existing study that the Agency has classified as acceptable or an existing study that has been submitted but not reviewed by the Agency (**Citing an Existing Study**). If I am citing another registrant's study, I understand that this option is available **only** for acute toxicity or certain efficacy data and **only** if the cited study was conducted on my product, an identical product or a product which EPA has "grouped" with one or more other products for purposes of depending on the same data. I may also choose this option if I am citing my own data. In either case, I will provide the **MRID or Accession number(s)** for the cited data on a "Product Specific Data Report" form or in a similar format. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" form (EPA Form 8570-29) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.
7. I request a waiver for this study because it is inappropriate for my product (**Waiver Request**). I am attaching a complete justification for this request, including technical reasons, data and references to relevant EPA regulations, guidelines or policies. [Note: any supplemental data must be submitted in the format required by P.R. Notice 86-5]. I understand that this is my **only** opportunity to state the reasons or provide information in support of my request. If the Agency approves my waiver request, I will **not** be required to supply the data pursuant to Section 3(c)(2)(B) of FIFRA. If the Agency denies my waiver request, I **must choose** a method of meeting the data requirements of this Notice by the due date stated by this Notice. In this case, I must, within **30 days** of my receipt of the Agency's written decision, submit a revised "Requirements Status and Registrant's Response" Form indicating the option chosen. I also understand that the deadline for submission of data as specified by the original data call-in notice will not change. By the specified due date, I will also submit: (1) a completed "**Certification With Respect To Data Compensation Requirements**" form (EPA Form 8570-29) and (2) two completed and signed copies of the **Confidential Statement of Formula (EPA Form 8570-4)**.

Items 10-13. Self-explanatory.

**NOTE:** You may provide **additional information** that does not fit on this form in a signed letter that accompanies this form. For example, you may wish to report that your product has already been transferred to another company or that you have already voluntarily canceled this product. For these cases, please supply all relevant details so that EPA can ensure that its records are correct.

**Page 1 of the Product Specific DCI is inserted here.**

**Page 2 of the Product Specific DCI is inserted here.**

**Page 3 of the Product Specific DCI is inserted here.**

**Page 4 of the Product Specific DCI is inserted here.**

**Page 5 of the Product Specific DCI is inserted here.**

**There is no tox batching for Mitin FF.**

**Attachment 5. List of All Registrants Sent This Data Call-In (insert) Notice**

Remove this page and insert the list of registrants sent this product specific DCI here.

## Instructions for Completing the Confidential Statement of Formula

The Confidential Statement of Formula (CSF) Form 8570-4 must be used. Two legible, signed copies of the form are required. Following are basic instructions:

- a. All the blocks on the form must be filled in and answered completely.
- b. If any block is not applicable, mark it N/A.
- c. The CSF must be signed, dated and the telephone number of the responsible party must be provided.
- d. All applicable information which is on the product specific data submission must also be reported on the CSF.
- e. All weights reported under item 7 must be in pounds per gallon for liquids and pounds per cubic feet for solids.
- f. Flashpoint must be in degrees Fahrenheit and flame extension in inches.
- g. For all active ingredients, the EPA Registration Numbers for the currently registered source products must be reported under column 12.
- h. The Chemical Abstracts Service (CAS) Numbers for all actives and inerts and all common names for the trade names must be reported.
- i. For the active ingredients, the percent purity of the source products must be reported under column 10 and must be exactly the same as on the source product's label.
- j. All the weights in columns 13.a. and 13.b. must be in pounds, kilograms, or grams. In no case will volumes be accepted. Do not mix English and metric system units (i.e., pounds and kilograms).
- k. All the items under column 13.b. must total 100 percent.
- l. All items under columns 14.a. and 14.b. for the active ingredients must represent pure active form.
- m. The upper and lower certified limits for all active and inert ingredients must follow the 40 CFR 158.175 instructions. An explanation must be provided if the proposed limits are different than standard certified limits.
- n. When new CSFs are submitted and approved, all previously submitted CSFs become obsolete for that specific formulation.

 United States Environmental Protection Agency Office of Pesticide Programs (TS-767) Washington, DC 20460		<b>A.</b> <input type="checkbox"/> Basic Formulation <input type="checkbox"/> Alternate Formulation		<b>B.</b> Page _____ of _____ See Instructions on Back	
2. Name and Address of Producer (Include ZIP Code)					
3. Product Name					
4. Registration No./File Symbol					
5. EPA Product Mgr./Team No.					
6. Country Where Formulated					
7. Pounds/Gal or Bulk Density					
8. pH					
9. Flash Point/Flame Extension					
10. Components in Formulation (List as actually introduced into the formulation. Give commonly accepted chemical name, trade name, and CAS number.)					
11. Supplier Name & Address					
12. EPA Reg. No.					
13. Each Component in Formulation					
14. Certified Limits % by Weight					
15. Purpose in Formulation					
16. Typed Name of Approving Official					
17. Total Weight 100%					
18. Signature of Approving Official					
19. Title					
20. Phone No. (Include Area Code)					
21. Date					





United States Environmental Protection Agency  
Washington, DC 20460

**CERTIFICATION OF OFFER TO COST  
SHARE IN THE DEVELOPMENT OF DATA**

Form Approved

OMB No. 2070-0106  
2070-0057

Approval Expires 3-31-96

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to Chief, Information Policy Branch, PM-223, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

**Please fill in blanks below.**

Company Name	Company Number
Product Name	EPA Reg. No.

I Certify that:

My company is willing to develop and submit the data required by EPA under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), if necessary. However, my company would prefer to enter into an agreement with one or more registrants to develop jointly or share in the cost of developing data.

My firm has offered in writing to enter into such an agreement. That offer was irrevocable and included an offer to be bound by arbitration decision under section 3(c)(2)(B)(iii) of FIFRA if final agreement on all terms could not be reached otherwise. This offer was made to the following firm(s) on the following date(s):

Name of Firm(s)	Date of Offer
-----------------	---------------

**Certification:**

I certify that I am duly authorized to represent the company named above, and that the statements that I have made on this form and all attachments therein are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under applicable law.

Signature of Company's Authorized Representative	Date
Name and Title (Please Type or Print)	

EPA Form 8570-32 (5/91) Replaces EPA Form 8580, which is obsolete

US EPA ARCHIVE DOCUMENT





**CERTIFICATION WITH RESPECT TO  
DATA COMPENSATION REQUIREMENTS**

Public reporting burden for this collection of information is estimated to average 15 minutes per response, including time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to, Chief Information Policy Branch, PM-233, U.S. Environmental Protection Agency, 401 M St., S.W., Washington, DC 20460; and to the Office of Management and Budget, Paperwork Reduction Project (2070-0106), Washington, DC 20503.

**Please fill in blanks below.**

Company Name

Company Number

Product Name

EPA Reg. No.

**I Certify that:**

1. For each study cited in support of registration or reregistratiion under the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA) that is an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter to cite that study.
2. That for each study cited in support of registration or reregistration under FIFRA that is NOT an exclusive use study, I am the original data submitter, or I have obtained the written permission of the original data submitter, or I have notified in writing the company(ies) that submitted data I have cited and have offered to: (a) Pay compensation for those data in accordance with sections 3(c)(1)(F) and 3(c)(2)(D) of FIFRA; and (b) Commence negotiation to determine which data are subject to the compensation requirement of FIFRA and the amount of compensation due, if any. The companies I have notified are. (check one)  
  
 The companies who have submitted the studies listed on the back of this form or attached sheets, or indicated on the attached "Requirements Status and Registrants' Response Form,"
3. That I have previously complied with section 3(c)(1)(F) of FIFRA for the studies I have cited in support of registration or reregistration under FIFRA.

Signature

Date

Name and Title (Please Type or Print)

**GENERAL OFFER TO PAY:** I hereby offer and agree to pay compensation to other persons, with regard to the registration or reregistration of my products, to the extent required by FIFRA section 3(c)(1)(F) and 3(c)(2)(D).

Signature

Date

Name and Title (Please Type or Print)



The following is a list of available documents for Mitin FF that may further assist you in responding to this Reregistration Eligibility Decision document. These documents may be obtained by the following methods:

Electronic

File format: Portable Document Format (.PDF) Requires Adobe® Acrobat or compatible reader. Electronic copies can be downloaded from the Pesticide Special Review and Reregistration Information System at 703-308-7224. They also are available on the Internet on EPA's gopher server, GOPHER.EPA.GOV, or using ftp on FTP.EPA.GOV, or using WWW (World Wide Web) on WWW.EPA.GOV., or contact Jeffrey Billingslea at (703)-308-8004.

1. PR Notice 86-5.
2. PR Notice 91-2 (pertains to the Label Ingredient Statement).
3. A full copy of this RED document.
4. A copy of the fact sheet for Mitin FF.

The following documents are part of the Administrative Record for Mitin FF and may be included in the EPA's Office of Pesticide Programs Public Docket. Copies of these documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet.

1. Health and Environmental Effects Science Chapters.
2. Detailed Label Usage Information System (LUIS) Report.

The following Agency reference documents are not available electronically, but may be obtained by contacting the person listed on the Chemical Status Sheet of this RED document.

1. The Label Review Manual.
2. EPA Acceptance Criteria